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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,378	02/12/2001	Patrick Hearing	STONYB-04970	9755

23535 7590 12/17/2003
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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,378

Applicant(s)

HEARING ET AL.

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 6-10 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 and 13 is/are allowed.
- 6) ☒ Claim(s) 1-5 and 14-19 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 9/25/2003, in which several claims were amended (claims 1-5, 11-19). Claims 1-19 are pending in the instant application, with claims 6-10 withdrawn without traverse from consideration as being directed to nonelected inventions.

The response filed 9/25/2003 has obviated the outstanding rejections under 35 U.S.C. 112 2nd paragraph. However, upon further review of the prior art it is apparent there remains an issue concerning a 102(a) reference that needs clarification. This is not a final action as the newly added grounds for rejection were not necessitated by applicants' amendment of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 15-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Gnatenko et al (Blood, 15 November 1999, Vol. 94, No. 10 SUPPL. Part 1, page 181a. Meeting Info: Forty-first Annual Meeting of the American Society of Hematology. New Orleans, Louisiana, USA, December 3-7, 1999). **This is a new rejection.**

The Gnatenko et al Abstract has common inventors but has a different inventive entity than the instant application.

In the information disclosure statement filed 4/9/2001 it is asserted that the Gnatenko et al reference differs from the recited claims in that the vectors of Gnatenko et al “do not comprise an adeno-associated virus terminal repeat sequence operably linked to the 3’ end of the nucleotide sequence of interest. Gnatenko et al.’s vectors are not disclosed to comprise the adeno-associated virus rep gene region.” (page 7, second paragraph).

Comparison of the teachings of the Gnatenko et al Abstract and the teachings of the instant specification indicate that the vectors used and the products obtained in each case are likely to be the same, however. For example, the initial constructs and host cells used to generate the mini-adenovirus vectors in the working examples of the instant specification are the same (e.g. Ad/AAV/GFP-Neo & Ad/AAV/FVIII in 293 cells; e.g. Working Examples 1-4). Further, new species of virus were generated that correspond in structural characteristics to those described in the instant specification (e.g. Figure 2). The Abstract teaches “Unexpectedly, excisional analyses using *rep*-expressing HeLa cell lines demonstrated novel species that cross-reacted with an Ad terminal repeat probe, suggesting the generation of a novel virus.” The size of the DNA found in the novel mAd/GFP-Neo virions were of similar size to those taught in the instant specification (e.g. ~4kb & 8kb; Figure 2C, Figure 3 of the instant specification). In both cases, the different novel products are referred to as monomers and dimers of the expression cassette flanked by duplicated flanking Ad packaging sequences (e.g. Figure 7). Gnatenko et al speculate that packaged genomes were presumably generated as a result of the unique structure of the AAV TR’s coupled with an intact Ad packaging signal.

Based upon these observations it appears the starting and finishing materials in the Gnatenko et al Abstract are the same as those disclosed in the instant specification as

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exemplifying the claimed invention. Further, it is unclear how one could generate the vectors described by Gnatenko et al (i.e. an intact transcription cassette retaining AAV terminal repeats) without using starting constructs having an AAV ITR "operably linked" to the sequence of interest in the expression cassette.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection.**

Claim 14 recites two cells present in the method in part (a), but only uses one of the two specified cells, making it unclear which is used and which is not. Thus, there is no antecedent basis for the term "said cell" in part (b).

Conclusion

Claims 12-13 are allowed. Claim 11 is objected to as being dependent upon a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

Ggl


GERRY LEFFERS
PRIMARY EXAMINER